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Sleep-promoting medications in children: physician prescribing habits in Southwestern Ontario, Canada

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ABSTRACT

Background: Research indicates that physicians may frequently use pharmacotherapy to treat pediatric insomnia despite minimal safety data and very limited indications. Canadian data on the subject are lacking. This study aimed to determine physicians' views on and prescribing habits for sleep-promoting over-the-counter medication (OTCM) and prescription (RXM) medications for children.

Methods: A modified 26-item version of the 'Pediatric Sleep Medication Survey', originally developed by Judith Owens and colleagues, was sent to 100 pediatricians and a random sample of 421 family physicians in Southwestern Ontario, Canada.

Results: A total of 67 returned surveys were sufficiently complete for analysis. Sixty-one respondents indicated their specialty (28 pediatricians, 33 family physicians). In a typical 6-month period, 89% and 66% of respondents have recommended OTCM and RXM, respectively, for children with sleep problems. Only 20% have received any formal training on pediatric sleep disorders. The most common circumstances and sleep problems for which OTCM or RXM were recommended were mood disorders, developmental delay and attention deficit hyperactivity disorder (ADHD) (56, 40, and 39%, respectively), and insomnia, bedtime struggles/delayed sleep onset and circadian rhythm disorders (52, 48, and 28%, respectively). A total of 30% recommended OTCM or RXM to otherwise healthy children with sleep problems. Melatonin (73%), OTC antihistamines (41%), antidepressants (37%), and benzodiazepines (29%) were the most commonly recommended OTCM and RXM, respectively.

Conclusions: Respondents in our sample frequently use pharmacotherapy to treat pediatric sleep problems; few have received any training in this area. Our findings indicate the need for evidence-based guidelines and regular physician training in the management of pediatric sleep disorders.

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1. Introduction

Insomnia is one of the most common pediatric health concerns and affects an estimated 30–40% of children and adolescents [1,2]. Children with underlying neurodevelopmental and psychiatric conditions have been reported to have prevalence rates of up to 80% [3].

Chronic insomnia disorder, based on the most recent third edition of the International Classification of Sleep Disorders, is defined as "persistent difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment,"

with symptoms occurring >3 nights per week for the previous three months [4]. There is strong evidence that inadequate sleep is associated with significant health problems, such as impaired cognitive functioning and academic performance, mood and behavioral disturbances including depression and increased suicidality in adolescents, obesity, and an increased frequency of accidents, including motor vehicle collisions [5,6]. The causes of pediatric insomnia are often multifactorial in nature and include behavioral and/or medical reasons; however, behavioral origins predominate. Behavioral insomnia of childhood is the most common cause of insomnia in infants and preschoolers, and inadequate sleep hygiene and psychophysiological insomnia predominate in older children and adolescents. As such, behavioral therapy is the mainstay of pediatric insomnia management [1,3]. Based on a limited number of studies, targeted pharmacotherapy in combination with behavioral therapy may be a consideration for certain groups of children with otherwise refractory insomnia, such as children with underlying

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neurodevelopmental or psychiatric conditions. However, as indicated in recent consensus statements, a solid evidence base and safety data for the use of sleep-promoting medications in the pediatric population is lacking [7,8]. In addition, there are no medications that are currently approved by the U.S. Food and Drug Administration for the treatment of pediatric insomnia. Despite this, emerging evidence indicates that more than half of American and European pediatricians and many general practitioners use pharmacotherapy to treat sleep disturbances in children and adolescents [9–11]. Furthermore, recent studies suggest that practitioner knowledge of diagnosing and managing sleep problems in children may be limited, in part due to a lack of formal training in the subject during medical school and residency, and that pharmacotherapy may often be used inappropriately [10,12]. Canadian data on the subject are lacking.

Therefore, the aim of this study was to determine the views and prescribing habits of a sample of family physicians and pediatricians with regard to sleep-promoting over-the-counter medications (OTCM) and prescription medications (RXM) for children in Southwestern Ontario, Canada.

2. Methods

2.1. Design and study population

In this cross-sectional study, a 26-item survey instrument (available on request) adapted from the *Pediatric Sleep Medication Survey* originally developed by Judith Owens and colleagues was sent between March and October 2013 to a sample of 100 pediatricians and 421 family physicians in Southwestern Ontario, Canada [9]. The province of Ontario, like the other Canadian provinces and territories, administers and delivers the majority of health services. As such, some aspects of healthcare delivery may vary between provinces; however, the overall healthcare system is comparable between them.

The sample of pediatricians consisted of members of the Canadian Paediatric Society practicing within the geographical area of the Southwestern Ontario Medical Education Network (SWOMEN), whose primary practices were not in intensive or emergency care. A random sample of family physicians practicing within the same region was created as follows: Postal codes of the designated survey area were randomly entered into the online physician registry search engine of the College of Physicians and Surgeons of Ontario with the 'Physician Type' filter set to 'Family Doctor', and the 'Registration Status' filter set to 'All Active Physicians'. From the lists populated for each of the entered postal codes, every fourth physician was chosen. A sample size four times larger was targeted to account for an anticipated lower response rate of family physicians in comparison to pediatricians.

To encourage participation, the study design included (i) monetary incentives (prize draw separate from the anonymous survey instrument with three prizes, first prize was a \$200 gift card from a well-known online seller); (ii) personalized mail-outs using special stamps and cover letters with hand-written salutations; (iii) a web-based version of the survey which participants could choose over the paper-based version; (iv) multiple return options (mail using the stamped return envelope provided, fax, online); (v) follow-up mail-outs that included replacement questionnaires; and (vi) reassurance of participant anonymity through wording on the cover letter and questionnaire.

The study was approved by the Western University Health Sciences Research Ethics Board.

2.2. Survey instrument

The 26-item survey consisted of three domains: (i) questions addressing the prevalence and type of sleep problems encountered

in the respondents' practice, specific conditions for which OTCM and RXM were recommended and reasons why sleep-promoting medications should or should not be recommended; (ii) questions exploring prescribing habits in a 6-month period (eg, number of patients and for which specific age groups OTCM and RXM had been recommended, which drug classes were preferred and typical treatment durations); and (iii) demographics, including practice-setting and medical training-related questions.

2.3. Survey distribution

Where email addresses were available, physicians were contacted by email containing a link to a web-based version of the survey. Otherwise, a print version of the survey was sent by regular mail with the cover letter providing the link to the web-based version for those preferring the electronic format. A second mailing following the same principles was sent six weeks later, a third one was sent three months after the first.

2.4. Exclusion criteria

Surveys were excluded from respondents who indicated that they did not see children, had their primary practices in intensive or emergency care, were retired or had answered none of the sleep medication-related questions as well as less than 60% of the survey items overall.

2.5. Statistical analysis

Data were analyzed using IBM SPSS Statistics, version 22.0. Continuous variables were expressed as means and standard deviation (SD), or as median and interquartile range (IQR) for skewed values. Percentages were used to summarize categorical variables.

3. Results

3.1. Sample characteristics

Seventy-eight surveys were returned (response rate 17%), and 67 met the inclusion criteria (Fig. 1).

Sixty-one respondents (91%) indicated their specialty (28 pediatricians, 33 family medicine), gender (48% female), primary practice location (64% urban, 8% suburban, 28% rural), and setting (30% hospital, 70% community based). Seventy-five percent were Caucasian, 19% Asian, and 2% African-American, Hispanic, or East Indian. In an average week, respondents provided direct patient care for 7 (SD 2.5) half-days and saw a median of 25 (IQR 19–50) children. Thirty-seven percent of respondents were in practice for <10 years, 25% for 10–20 years, and 31% for over 20 years. Only 19.7% of respondents had received any formal training on diagnosing and treating sleep disorders (25% of pediatricians, 15% of family physicians). The mean number of years since graduation of these providers was 20.9 (SD 12.6).

3.2. Provider recommendations of sleep-promoting medication

Overall, in a typical 6-month period, 88.9% of respondents recommended OTCM, and 66.1% recommended RXM for children with sleep problems. A median of 5% (IQR 1–10) of pediatric patients in the respondents' practices had significant problems falling or staying asleep. The three most common indications and specific sleep disorders for which sleep-promoting OTCM or RXM were recommended in children were (i) mood disorders, developmental delay and attention deficit hyperactivity disorder (ADHD) and (ii) insomnia, bedtime struggles/sleep-onset delay, and circadian rhythm disorders.

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